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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,239	VAN NORREN ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-39* is/are pending in the application.

4a) Of the above claim(s) *20-22,26,27 and 30-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23-25,28-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that the 4/1/10 reply filed by applicant states 'In response to the final office action dated October 1 2009 applicants submit this amendment together with a petition for a three-month extension of time and request for continued examination ("RCE").'

However, the office action dated 10/1/09 was not a final office action. Section 706.07(h) of the MPEP states that "37 CFR 1.114 provides a procedure under which an applicant may obtain continued examination of an application in which prosecution is closed (e.g., the application is under final rejection or a notice of allowance)". In the instant case the office action dated 10/1/09 was not a final rejection or a notice of allowance. Thus the RCE filing was improper since the prosecution was not closed. In order to advance prosecution the reply filed 4/1/10 was treated as a standard reply to a non-final office action.

Applicants amendments and arguments filed 4/1/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Briefly, the claim amendments have overcome the previous 102 rejections.

Applicant's previously elected (2/22/08) with traverse Group II (claims 19-29) and the following species:

Guanosine equivalent (GTP increasing component) – GUANOSINE

Carbohydrate – GLUCOSE

(no other species were identified for the composition).

As discussed below, the elected species were found in the prior art. Any art that was uncovered during the search for the elected species that reads on non-elected species is also cited herein. In accord with section 803.02 of the MPEP the claims to the elected species are rejected and claims to nonelected species held withdrawn.

Claims 1-18 have been cancelled.

Claims 30-36 are to a non-elected group. Since applicants elected guanosine and glucose as the species, claims 20-22,26-27,37-39 which include additional components are to nonelected species (the restriction requirement 1/22/08 page 4 expressly stated that applicants could elect multiple components of the composition).

Claims 30-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/08.

Claims 20-22,26-27,37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/08.

Claims 19,23-25,28-29 are under consideration.

Claim Rejections - 35 USC § 112

This rejection is necessitated by applicants amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 refers to 'mammal suffering from…', 'that suffers or will suffer from', and 'within 24 hours of the occurrence'. It is unclear if the patient has already suffered trauma or if the treatment is a preventative treatment such that the patient has not yet suffered a trauma. In other words, it is unclear to whom the composition is administered - a patient who has suffered trauma or a patient who has not suffered trauma. Since the claims recite 'mammal suffering from…' the claims suggest that the mammal has already suffered from a trauma. However, the recitations of 'that suffers or will suffer from', and 'within 24 hours of the occurrence' suggest otherwise. The claims provide contradictory information about the patient population – the mammal is 'suffering from trauma' and 'will suffer from said trauma'. The dependent claims do not clarify the scope of the claim. Administration to a patient who has not suffered trauma is separate from administration to a patient who has suffered trauma.

Although unclear (see 112 2nd) the claims have been interpreted such that the mammal has suffered trauma and that the administration occurs after the trauma (the claims expressly recite 'mammal suffering from'). The claims have been interpreted such that they contain no new matter.

Claim Rejections - 35 USC § 103

Claims were previously rejected under 103 based on the reference cited below. Since the claims have been updated and updated rejection corresponding to the instant claims is recited below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 5,231,085; first cited with 4/29/08 office action).

Alexander teach that nutritional therapy by enteral administration is known in the art and that the compromise of the immune system may lead to complications due to multiple organ failure (column 1 lines 19-31). Alexander teach a specific composition (example 1 column 6)

which includes a carbohydrate source and guanine. Alexander teach the administration of compositions (examples 2 and 3). Specifically the compositions are taught to be suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36). In example 2 (column 6 line 63-64) the patients have experienced trauma or major general surgery and in example 3 (column 9 lines 3-4) the patients have undergone major operation. In example 2, the patients are administered composition A (column 7 line 46-47). The amount of composition A was calculated based on energy expenditure (column 7 line 51-55). Alexander teach that the daily amount is usually 1000-2000 kcal/day (column 4 line 10-12). Composition A includes 197.6 g of carbohydrate (in 1500ml so the concentration is 132 g/l) and 0.56-0.77g guanine. Alexander teach enteral administration and liquid compositions (column 9 line 10-11 and column 3 line 56-62 for example).

Composition A as taught by Alexander includes guanine, not guanosine as recited in the instant claims.

Alexander teach a nucleobase or nucleoside (claim 1b, column 2 lines 50-60) as part of the composition. In composition A (column 6) Alexander uses the nucleobase guanine. Alexander teach guanosine as a specific nucleoside (column 2 lines 59-60). Since Alexander teach nucleosides, specifically guanosine, as the nucleobase source one would be motivated to substitute guanine as described in composition A (column 6) with guanosine. Since Alexander teach the administration of composition A (examples 2 and 3) one would be motivated to administer this composition in which guanosine is substituted for guanine. One would have a reasonable expectation of success since Alexander expressly teach that the nucleobase source can

be nucleobases or nucleosides (column 2 lines 50-60). In example 2, the patients are administered composition A (column 7 line 46-47). The amount of composition A was calculated based on energy expenditure (column 7 line 51-55). Alexander teach that the daily amount is usually 1000-2000 kcal/day (column 4 line 10-12) thus one would be motivated to use such amount as an initial amount. Composition A includes 197.6 g of carbohydrate (in 1500ml so the concentration is 132 g/l) and 0.56-0.77g guanine (or guanosine). Further, Alexander recognizes glucose, applicants elected species, as a carbohydrate source (column 7 line 25 for example) thus one would be motivated to use glucose as the carbohydrate source. Thus Alexander motivate the use of guanosine and glucose in the composition at the doses and concentrations as recited in claims 19,28-29.

Alexander specifically teach that the compositions are suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36). In example 2 (column 6 line 63-64) the human patients have experienced trauma or major general surgery and in example 3 (column 9 lines 3-4) the patients have undergone major operation. Thus one would be motivated to identify such patients and administer the composition to patients who have undergone surgery as recited in the instant claims 19,23-24. Alexander expressly teach that the nutritional supplementation begins within 24 hours of the injury (column 7 lines 21-23) thus meeting the time frame as recited in the instant claims. Further, since example 3 (column 8 lines 66-67) states that the formulation is for patients undergoing major operation one would be motivated to administer the formulation prior to the scheduled operation as recited in instant claim 25 to enhance the immune system as taught by Alexander (claim 1). Alexander teach enteral

administration and liquid compositions (column 9 line 10-11 and column 3 line 56-62 for example) as recited in the instant claims.

It is noted that the claims state that the method is for 'reducing the risk of developing organ dysfunction'. Alexander teach that nutritional therapy by enteral administration is known in the art and that the compromise of the immune system may lead to complications due to multiple organ failure (column 1 lines 19-31). Thus Alexander recognize multiple organ dysfunction as a problem. Further, Alexander obviate the active steps using the claimed components.

The claims would have been obvious because the substitution of one known element (guanosine) for another (guanine) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. In fact, Alexander expressly teach that the nucleobase source can be nucleobases (such as guanine) or nucleosides (such as guanosine) (column 2 lines 50-60). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Although unclear (see 112 2nd) the claims have been interpreted such that the mammal has suffered trauma and that the administration occurs after the trauma (the claims expressly recite 'mammal suffering from'). The claims have been interpreted such that they contain no new matter. Alexander teach in one example (column 7 liines 21-23) that administration was within 24 hours of injury as recited in the instant claims.

Response to Arguments 103 rejection

Applicants argue (pages 8-9) that Alexander is directed to stimulating the immune system after trauma which is different from the recited multiple organ dysfunction.

Applicants argue that compound A (which is presumed to be composition A) does not contain guanosine, that Alexander only mentions a carbohydrate source, and that there is no reason to pick the components or a reason to have expected them to be useful.

Applicants argue that Alexander teach administration approximately 24 hours after surgery which is different than the recitation of claim 25.

Applicant's arguments filed 4/1/10 have been fully considered but they are not persuasive.

Although Applicants argue (pages 8-9) that Alexander is directed to stimulating the immune system after trauma which is different from the recited multiple organ dysfunction, it is noted that claim 19 recites that the method is for 'reducing the risk of developing organ dysfunction'. Thus the intended use is to reduce the risk of developing organ dysfunction. The intended use does not require a manipulative difference and thus does not limit the claim (MPEP 2111.02 II). In other words, the claims do not require the patient to have multiple organ dysfunction. Further, Alexander expressly recognize multiple organ failure as a patient population of interest (column 1 lines 28-31).

Although Applicants argue that compound A (which is presumed to be composition A) does not contain guanosine, that Alexander only mentions a carbohydrate source, and that there is no reason to pick the components or a reason to have expected them to be useful, Section 2123 of the MPEP states that alternative embodiments are not a teaching away. In the instant case,

Alexander teach glucose, applicants elected species, as a carbohydrate source in one of the examples (column 7 line 25 for example). Thus, Alexander more than just merely mentions a carbohydrate source as asserted by applicant. Alexander teach a nucleobase or nucleoside (claim 1b, column 2 lines 50-60) as part of the composition. In composition A (column 6) Alexander uses the nucleobase guanine. Alexander teach guanosine as a specific nucleoside (column 2 lines 59-60). Since Alexander teach nucleosides, specifically guanosine, as the nucleobase source one would be motivated to substitute guanine as described in composition A (column 6) with guanosine. It is noted that guanosine and guanine share many structural features and they share a common core structure. In other words, guanosine is the nucleoside and guanine is the nucleobase. Alexander expressly teach a nucleobase or nucleoside (claim 1b, column 2 lines 50-60). Since Alexander teach the administration of composition A (examples 2 and 3) one would be motivated to administer this composition in which guanosine is substituted for guanine. In other words, based on the teachings and specific examples one would be motivated to use guanosine. One would have a reasonable expectation of success since Alexander expressly teach that the nucleobase source can be nucleobases or nucleosides (column 2 lines 50-60). Further, Alexander expressly teach the compositions as immunostimulatory (abstract, claim 1). Alexander specifically teach that the compositions are suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36). It is noted that obviousness does not require absolute predictability (MPEP section 2143.02 II).

Although Applicants argue that Alexander teach administration approximately 24 hours after surgery which is different than the recitation of claim 25, Alexander teach in one example (column 7 liines 21-23) that administration was within 24 hours of injury. Section 2123 of the

MPEP states that alternative embodiments are not a teaching away. Thus one would be motivated to administer the appropriate composition at the appropriate time in order to meet the goal of treating the patient. As discussed above (see 112 2nd) the claims are unclear. Claim 19 expressly states 'mammal suffering from…'. Thus it is seems contradictory that applicants are arguing about 'prior to the occurrence'.

Prior Art

The prior art previously made of record and not relied upon is considered pertinent to applicant's disclosure:

Bistrian et al US 5,320,846. Bistrian teach methods of enterally administering guanosine (claim 1) to patients having trauma or surgery (claim 2). Bistrian teach a carbohydrate source with the formulation (claim 3).

Hageman et al US 6,420,342. Hageman teach nutritional compositions for trauma and surgery (abstract, claim 12). Hageman teach compositions with ribose (abstract, claim 1) and carbohydrates such as glucose (column 7 lines 10-30). Hageman teach enteral formulations (column 6 line 45).

Conclusion

The 112 2nd rejection is necessitated by applicants amendments. A 103 rejection based on the reference cited herein appeared in the previous office action. Since the claims have been amended the rejection has been updated.

As discussed above, the RCE filed on 4/1/10 was improper and has been treated as a standard reply to the non-final rejection of 10/1/09.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654